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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/717,288	11/18/2003	Edward William Adams	7725-0001.01	7573

23980 7590 06/30/2004

REED & EBERLE LLP
800 MENLO AVENUE, SUITE 210
MENLO PARK, CA 94025

EXAMINER

LE, HOA T

ART UNIT	PAPER NUMBER
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1773

DATE MAILED: 06/30/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/717,288	Applicant(s) ADAMS ET AL	
	Examiner H. T. Le	Art Unit 1773	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-271 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1 and 86-271 is/are rejected.
- 7) ☒ Claim(s) 2-85 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>11/2003</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Double Patenting

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claim 1 is provisionally rejected under the judicially created doctrine of double patenting over claims 40 and 41 of U.S. Patent No. 6,649,138. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both instant claim 1 and patent claims are directed to the same water-dispersible nanoparticle comprising the same inner core, the same organic coating, the same outer layer of a multiply amphipathic polymer which comprises a functional group covalently bonded to the polymer through a linking moiety. The only difference between the instant claim 1 and the patent claims is that in claim 1, oxyalkylene is

named as the linking moiety. However, the patent gives only oxyalkylene as an example for the linking moiety (see patent, col. 18, lines 35-36). Therefore, oxyalkylene is, in essence, implicitly claimed to be the linking moiety in the patent claim.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schmeller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

3. Claims 86-129 are provisionally rejected under the judicially created doctrine of double patenting over claims 1-45 of copending Application No. 10/716,971. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both sets of claims are directed to the same conjugate of an affinity molecule and a water-dispersible nanoparticle, wherein the water dispersible nanoparticle comprises the same inner core, the same organic coating, the same outer layer of a multiply amphipathic polymer, and a functional group linked to the polymer, and further wherein the affinity molecule is bound to the functional group. The only difference between the instant claims and the reference claims is that in the instant claims, oxyalkylene is named as the linking moiety. However, the reference application gives only

alkylene or oxyalkylene as examples for the linking moiety (see application 10/716,971, last sentence of page 21). Therefore, oxyalkylene is, in essence, implicitly claimed to be the linking moiety in the reference claims.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

4. Claims 130-178 are provisionally rejected under the judicially created doctrine of double patenting over claims 46-95 of copending Application No. 10/716,971. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both sets of claims are directed to the same composition comprising the same conjugates of an affinity molecule and a water-dispersible nanoparticle, wherein the water dispersible nanoparticle comprises the same inner core, the same organic coating, the same outer layer of a multiply amphipathic polymer, and a functional group linked to the polymer, and further wherein the affinity molecule is bound to the functional group. The only difference between the instant claims and the reference claims is that in the instant claims, oxyalkylene is named as the linking moiety. However, the

reference application gives only alkylene or oxyalkylene as examples for the linking moiety (see application 10/716,971, last sentence of page 21). Therefore, oxyalkylene is, in essence, implicitly claimed to be the linking moiety in the reference claims.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schmeller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

5. Claims 179-222 are provisionally rejected under the judicially created doctrine of double patenting over claims 96-140 of copending Application No. 10/716,971. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both sets of claims are directed to the same nanoparticle conjugate of an affinity molecule and a water-dispersible nanoparticle, wherein the water dispersible nanoparticle comprises the same inner core, the same organic coating, the same outer layer of a multiply amphipathic polymer, and a functional group linked to the polymer, and further wherein the affinity molecule is bound to the functional group. The only difference between the instant claims and the reference claims is that in the instant claims, oxyalkylene is named as the linking moiety. However, the reference application gives

only alkylene or oxyalkylene as examples for the linking moiety (see application 10/716,971, last sentence of page 21). Therefore, oxyalkylene is, in essence, implicitly claimed to be the linking moiety in the reference claims.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

6. Claims 233-271 are provisionally rejected under the judicially created doctrine of double patenting over claims 141-189 of copending Application No. 10/716,971. This is a provisional double patenting rejection since the conflicting claims have not yet been patented.

The subject matter claimed in the instant application is fully disclosed in the referenced copending application and would be covered by any patent granted on that copending application since the referenced copending application and the instant application are claiming common subject matter, as follows: Both sets of claims are directed to the same composition comprising the same nanoparticle conjugates each comprising an affinity molecule and a water-dispersible nanoparticle, wherein the water dispersible nanoparticle comprises the same inner core, the same organic coating, the same outer layer of a multiply amphipathic polymer, and a functional group linked to the polymer, and further wherein the affinity molecule is bound to the functional group. The only difference between the instant claims and the reference claims is that in the instant claims, oxyalkylene is named as the

linking moiety. However, the reference application gives only alkylene or oxyalkylene as examples for the linking moiety (see application 10/716,971, last sentence of page 21). Therefore, oxyalkylene is, in essence, implicitly claimed to be the linking moiety in the reference claims.

Furthermore, there is no apparent reason why applicant would be prevented from presenting claims corresponding to those of the instant application in the other copending application. See *In re Schmedler*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Allowable Subject Matter

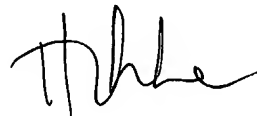
7. Claims 2-85 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. References are cited as art of interest.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to H. T. Le whose telephone number is 571-272-1511. The examiner can normally be reached on 10:00 a.m. to 6:30 p.m., Mondays to Friday.

The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



H. T. Le
Primary Examiner
Art Unit 1773